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DEPARTMENT OF HEALTH & HUMAN SERVICES

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-09

January 25, 2001

Mr. Roger Masselink, Owner
Roger Masselink Dairy
10718 Green Lake Road
Middleville, MI 49333

Dear Mr. Masselink:

An investigation at your dairy farm, conducted by Investigators Kelly Clark and Leslie A. Paul on November 9, 2000, confirmed that you offered animals for sale for slaughter as food in violation of sections 402 (a) (2) (C) (ii) and 402 (a) (4) of the Federal Food, Drug, and Cosmetic Act.

On or about September 19, 1999, you sold a bob veal calf, identified as originating from your farm, for slaughter as human food at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of sulfamethoxzole residue (4.00 ppm in the muscle and 2.20 ppm in the liver) and streptomycin residue (0.71 ppm in the liver, 3.50 ppm in the kidney, and 0.65 ppm in the muscle). A tolerance level of 0.0 ppm in the muscle and liver has been established for residues of sulfamethoxzole, and a tolerance level of 0.5 ppm in the liver, kidney, and muscle has been established for residues of streptomycin in the edible tissues of a bob veal calf. The presence of these drugs in edible tissue from this animal causes the food to be adulterated.

On or about November 19, 1997, you sold a bob veal calf, identified as originating from your farm, for slaughter as human food at [redacted] USDA analysis of tissue samples collected from that animal identified the presence of gentamicin residue (0.57 ppm in the liver and 1.60 ppm in the kidney). A tolerance level of 0.0 ppm in the liver and kidney has been established for residues of gentamicin in the edible tissues of a bob veal calf. The presence of this drug in edible tissue from this animal causes the food to be adulterated.

Our investigation also found that you hold animals under conditions which are so inadequate that diseased animals and/or medicated animals bearing potentially

harmful drug residues are likely to enter the food supply. Our investigation found that you lack an adequate system for assuring that animals have been treated only with drugs which have been approved for use in those species, for assuring that drugs are used in a manner not contrary to the directions contained in the labeling, and for assuring that animals medicated by you have been withheld from slaughter for the appropriate period of time to permit depletion of potentially hazardous drug residues from edible tissues. Food from animals held under such conditions is adulterated.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operations and the food you distribute are in compliance with the law.

You should take prompt action to correct these violations and to establish procedures to prevent their recurrence. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Please submit your response to: Mr. David M. Kaszubski
Director Compliance Branch
U. S. Food & Drug Administration
1560 East Jefferson Ave.
Detroit, MI 48207-3179

Sincerely yours,

John P. Dempster for

Raymond V. Mlecko
District Director
Detroit District